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PATENT
Docket No.: 082368-003610US
Client Ref. No.: ONC-A0217Y1P2-US

TOWNSEND and TOWNSEND and CREW LLP

By: /Megan McCoy/
Megan McCoy

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

NAKAMURA and KATAGIRI

Patent No.: 7,601,826

Issued: October 13, 2009

Application No.: 10/529,592

Filed: March 24, 2006

For: GENES AND POLYPEPTIDES
RELATING TO HUMAN PANCREATIC
CANCERS

Customer No.: 20350

Confirmation No.: 4468

Examiner: GODDARD, Laura B.

Art Unit: 1642

**REQUEST FOR
RECONSIDERATION OF PATENT
TERM ADJUSTMENT
DETERMINATION
UNDER 37 C.F.R. § 1.705(d)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Pursuant to 37 C.F.R. § 1.705(d), Applicants respectfully request reconsideration of the patent term adjustment determination. This request is accompanied by the fee set forth in §1.18(e) and a statement of facts as required under 37 C.F.R. § 1.705(b)(2).

In view of the following it is respectfully requested that Applicants be granted a corrected patent term adjustment of **885 days**.

Statement of Facts as required under 37 C.F.R. § 1.705(b)(2)

The correct patent term adjustment is 885 days, not 397 days as stated on the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) listed on the front page of U.S. Patent No. 7,601,826, issued October 13, 2009.

The period of adjustment under § 1.702(a) is 399 days ("A delay").

The period of adjustment under § 1.702(b) is 562 days ("B delay").

The period of adjustment under § 1.704(a) is 2 days ("applicant delay").

The period of adjustment under § 1.703(f) is 885 days.

The Relevant Dates as Specified in 37 C.F.R. §§ 1.703(a)-(e) , §§ 1.704 and the Adjustment Specified in 37 C.F.R. § 1.703(f)

1. § 1.703(a) as applied to U.S. National Stage Applications under § 371

Applicants do not dispute that the Office did correctly calculate the term adjustments to include the term adjustments that Applicants are entitled to under 37 CFR § 1.703(a) for a U.S. National Stage Application under § 371 as a total of 399 days as shown on the attached **Exhibits A** (Patent Term Adjustment History) and **C** (Applicant PTA Calculation). This period of time began on March 24, 2006 (date § 371(c) requirements satisfied) and ended on June 12, 2008 when a Restriction Requirement was mailed by the Office.

2. § 1.703(b) as applied to U.S. National Stage Applications under § 371

The Office failed to issue a patent within three years of the actual filing date of the above-referenced application. Applicants **do** dispute the Office's calculation of 0 days of term adjustments that Applicants are entitled to under 37 CFR § 1.703(b) and under § 1.702(b) (*see* "PTA 36 Months" in **Exhibit A**).

The present application is the U.S. National Stage entry under 35 U.S.C. § 371 of International Application No. PCT/JP2003/011713, filed September 12, 2003, which claims the benefit of priority of U.S. Provisional Application No. 60/414,872, filed September 30, 2002 and U.S. Provisional Application No. 60/450,889, filed February 28, 2003 (*see* face page of U.S. Patent No. 7,601,826 (**Exhibit B**)). Applicants submit that the "actual filing date" of a U.S.

national stage application filed under 35 U.S.C. § 371, for purposes of calculating "B Delay" under 35 U.S.C. § 154(b)(1)(B), 37 C.F.R. § 1.702(b) and § 1.703(b), is the date that is 30 months from the priority date of the international application. Therefore, pursuant to the provisions of 35 U.S.C. § 371(b) and (f), the national stage for the present application "commenced" on March 30, 2005, i.e., upon expiration of 30 months from the priority date of the international application and no express request for entry was made under § 371(f).

As a result, the period beginning on April 1, 2008 (the day after the date that is three years after March 30, 2005, the date that the national stage commenced), and ending on October 13, 2009 (the date the instant U.S. Patent issued), is 562 days in length. Thus, the effective period of adjustment as applied under 37 C.F.R. § 1.702(b) is **562 days**.

Applicants submit that the Office erred in its calculation of the three-year pendency provision under 35 U.S.C. § 154(b)(1)(B) since the Office failed to take into account that the date that determines the three-year provision was the commencement date as defined by 35 U.S.C. § 371(b) and (f). Instead, the Office used the 35 U.S.C. § 371(c) date of March 24, 2006 as its "filing" date (*see Exhibits A and B*) for purposes of calculating "A Delay" and "B Delay". Therefore, the date the Office used as its three-year date was March 24, 2009 instead of the appropriate April 1, 2008 date. Thus, the Office's determination of "B Delay" was from March 24, 2009 through October 13, 2009 for a total of 203 days. The Office still contends, despite the ruling in the *Wyeth* court (D.D.C. 2008), that the term adjustment is the greater of the "A" delay or "B" delay period. Therefore, the instant U.S. Patent was denied its appropriate "B" delay term of 562 days and the "A" delay of 399 days was used.

3. § 1.703(c)-(e)

There are no relevant dates as specified under §§ 1.703(c)-(e).

4. Overlapping periods under § 1.703(a)-(e)

Applicants have calculated overlapping periods in accordance with *Wyeth v. Dudas* (88 U.S.P.Q.2d 1538, D.D.C. 2008). Periods of delay under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §1.54(b)(1)(B) overlap only if they occur on the same calendar day or days (*see Wyeth*). Applicants submit that there are **74 days** of overlap under § 1.703(a)-(e) which include the April 1, 2008 three-year date through the June 12, 2008 date of mailing of a Restriction

Requirement (*see Exhibit C*). Therefore the “A Delay” was still occurring on April 1, 2008 (start of “B Delay”) and ended when a first action on the merits was mailed from the Office on June 12, 2008.

5. Reduction of Period of Adjustment of Patent Term Under 37 C.F.R. §1.704

Applicants do not dispute the calculation by the Office of the period of adjustment under § 1.704(a) as total of 2 days indicated by the attached Patent Term Adjustment History (*see Exhibits A and C*).

6. § 1.703(f)

The period of adjustment under 37 C.F.R. § 1.702(f) is as follows:

Type “A” delay:	399 days
Type “B” delay:	562 days
“A” and “B” overlap:	74 days
Applicant delay	2 days
<u>Adjusted</u>	<u>885 days</u>

Terminal disclaimer

The instant application is not subject to a terminal disclaimer.

PATENT TERM ADJUSTMENT DETERMINATION

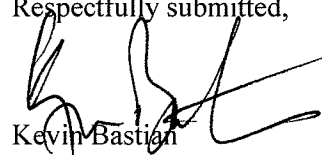
Pursuant to *Wyeth* and the provisions regarding § 371 applications, Applicants are entitled to 885 days of patent term adjustment, *i.e.*:

[961 days (A delay + B delay) minus 74 overlap days] minus [2 days (applicant delay)].

Based on the foregoing, Applicants respectfully request reconsideration of the patent term adjustment determination.

Please charge the fee set forth in 37 C.F.R. §1.18(e) (\$200.00) to Deposit Order Account No. 20-1430. Please charge any necessary additional fees or credit any overpayments to our Deposit Order Account No. 20-1430.

Respectfully submitted,



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EXHIBIT A

10/529,592	GENES AND POLYPEPTIDES RELATING TO HUMAN PANCREATIC CANCERS	12-04- 2009::20:25:12
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/529,592

Filing or 371(c) Date:	03-24-2006	USPTO Delay (PTO) Delay (days):	399
Issue Date of Patent:	10-13-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	2
Post-Issue Petitions (days):	+0	Total PTA (days):	397
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
09-23-2009	PTA 36 Months		
10-13-2009	Patent Issue Date Used in PTA Calculation	End of "B" delay period	Applicants DO NOT Agree
09-04-2009	Dispatch to FDC		
09-03-2009	Application Is Considered Ready for Issue		
08-31-2009	Applicant Has Filed a Verified Statement of Small Entity Status in Compliance with 37 CFR 1.27		
08-31-2009	Issue Fee Payment Verified		2
08-31-2009	Issue Fee Payment Received		↑
06-16-2009	Sequence Forwarded to Pubs on Tape		↑
05-29-2009	Mail Notice of Allowance	14	
05-26-2009	Document Verification	↑	
05-26-2009	Notice of Allowance Data Verification Completed	↑	
05-26-2009	Case Docketed to Examiner in GAU	↑	
05-26-2009	Examiner's Amendment Communication	↑	
03-20-2009	Date Forwarded to Examiner	↑	
01-15-2009	Response after Non-Final Action	↑	
10-15-2008	Mail Non-Final Rejection		
10-14-2008	Non-Final Rejection		
03-07-2008	Information Disclosure Statement considered		
07-20-2007	Information Disclosure Statement considered		
03-24-2006	Information Disclosure Statement considered		
08-16-2008	Date Forwarded to Examiner		
07-11-2008	Response to Election / Restriction Filed		
06-12-2008	Mail Restriction Requirement	385	
06-09-2008	Requirement for Restriction / Election	↑	
03-07-2008	Information Disclosure Statement (IDS) Filed	↑	
03-07-2008	Information Disclosure Statement (IDS) Filed	↑	
08-16-2007	Case Docketed to Examiner in GAU	↑	
07-20-2007	Information Disclosure Statement (IDS) Filed	↑	
07-20-2007	Information Disclosure Statement (IDS) Filed	↑	
09-19-2006	IFW TSS Processing by Tech Center Complete	↑	

EXHIBIT A -- cont'd

03-24-2006	Reference capture on IDS	↑
03-24-2006	Information Disclosure Statement (IDS) Filed	↑
03-24-2006	Information Disclosure Statement (IDS) Filed	↑
→ 03-24-2006	371 Completion Date ←	↑
08-30-2006	Application Dispatched from OIPE	
03-24-2006	Additional Application Filing Fees	
03-24-2006	Information Disclosure Statements	
03-24-2006	A set of symbols and procedures, provided to the PTO on a set of computer listings, that describe in	
03-24-2006	CRF Disk Has Been Received by Preexam / Group / PCT	
03-24-2006	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	
08-14-2006	CRF Is Good Technically / Entered into Database	

Close Window



US007601826B2

(12) **United States Patent**
Nakamura et al.

(10) **Patent No.:** **US 7,601,826 B2**
(45) **Date of Patent:** **Oct. 13, 2009**

(54) **GENES AND POLYPEPTIDES RELATING TO HUMAN PANCREATIC CANCERS**

(75) Inventors: **Yusuke Nakamura**, Yokohama (JP);
Toyomasa Katagiri, Shinagawa-ku (JP)

(73) Assignee: **Oncotherapy Science, Inc.**, Kanagawa (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 397 days.

(21) Appl. No.: **10/529,592**

(22) PCT Filed: **Sep. 12, 2003**

(86) PCT No.: **PCT/JP03/11713**

§ 371 (c)(1),
(2), (4) Date: **Mar. 24, 2006**

(87) PCT Pub. No.: **WO2004/031411**

PCT Pub. Date: **Apr. 15, 2004**

(65) **Prior Publication Data**

US 2006/0270619 A1 Nov. 30, 2006

Related U.S. Application Data

Start of (60) Provisional application No. 60/414,872, filed on Sep.
30-mo. ← 30, 2002, provisional application No. 60/450,889,
filed on Feb. 28, 2003.

priority

(51) Int. Cl.
C07H 21/00 (2006.01)
C12N 15/00 (2006.01)
C12N 5/00 (2006.01)

371 (b)

date:

(52) U.S. Cl. **536/23.5**; 536/23.1; 435/320.1;
435/325

3/30/2005

(58) **Field of Classification Search** None
See application file for complete search history.

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(Continued)

Primary Examiner—Laura B Goddard

(74) Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP

(57) **ABSTRACT**

The present application provides novel human genes C1958V1 or C1958V2 whose expression is markedly elevated in pancreatic cancers compared to corresponding non-cancerous tissues. The genes and polypeptides encoded by the genes can be used, for example, in the diagnosis of pancreatic cancer, and as target molecules for developing drugs against the disease.

5 Claims, 6 Drawing Sheets

EXHIBIT C

PTA Calculation Table – 371 / Wyeth version

Client Matter No. 082368-003610US

Application No. 10/529,592 (Now US Patent No. 7,601,826, issued October 13, 2009)

For: *GENES AND POLYPEPTIDES RELATING TO HUMAN PANCREATIC CANCERS*

Additions to the PTA (PTO)	Deductions to the PTA (Applicant)
Date of Nat'l Phase (§371) Filing: 03/29/2005 Date §371(c) requirements fulfilled: 03/24/2006 1st OA: 06/12/2008 14 month Deadline*: 05/24/2007 (*based upon §371(c) date) <u>Over 14 months: +385 days ("A")</u> 3-year deadline**: 03/30/2008 (**based upon §371(b) date) Date Patent Issued: 10/13/2009 <u>Over 3 years +562 days ("B")</u> OVERLAP: 1 st OA (6/12/2008) occurred <u>after</u> the 3/30/2008 3-yr deadline; therefore <u>74 days</u> are overlap	Date of OA: 6/12/2008 Date of Response: 7/11/2008 Over 3 months: 0 days Date of OA: 10/15/2008 Date of Resp.: 1/15/2009 Over 3 months: 0 days
Date of Reply: 1/15/2009 Date of Not. Allow: 5/29/2009 Over 4 months: <u>+14 days</u>	Date of Not. Allow: 5/29/2009 Date Issue Fee Paid: 8/31/2009 Over 3 months: <u>-2 days</u>
"A" PTA: +399 days "B" PTA: +562 days Overlap days: -74 days	
(399 + 562)**- 74 overlap days= + 887 days	Applicant Delay: - 2 days
non-Wyeth PTA (OLD PTO Calc.) = + 397 ("A" days) non-Wyeth PTA (371 error) = +560 ("B" days) 371 PTO error + Wyeth PTA = + 885 ("A+B" days)	

***"A" + "B" dates cannot occur on the same date.